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Attorney Docket No: 10123/00801 (03-325)

REMARKS

New claims 20 and 21 have been added. Claims 1 - 21 are now pending in the present application. No new matter has been added. In view of the following remarks, it is respectfully submitted that all of the pending claims are allowable.

Claims 1 - 19 stand rejected under 35 U.S.C. § 102(b) as anticipated by Mikhail (U.S. Patent 5,707,357). Although the Examiner first stated that claims 1 - 9, rather than claims 1-19, are rejected as anticipated by Mikhail, he concluded that Mikhail discloses every element of claims 1 - 19. Therefore, applicants have addressed this as a rejection of claims 1 - 19.

Claim 1 recites "[a] pressure actuated valve for controlling the flow of fluid through a medical device," which includes "a flow control membrane... including a plurality of slits extending therethrough, wherein, when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen." (See Specification, ¶¶ [0016] - [0017].) In contrast, Mikhail discloses a catheter comprising "a palpitatable valve that may be selectively manipulated by the patient." (Mikhail, col. 6, ll. 2-4.) That is, the valves of Mikhail are opened only through manual actuation -- squeezing the valve. Any opening of the valve of Mikhail due to fluid pressure represents a failure of the device which is designed to allow the release of urine from the bladder only when specifically desired by the user. That is, the valve of Mikhail is designed to remain sealed at all times regardless of the pressure applied thereto. (See Mikhail, col. 2, ll. 8-21.) Therefore, it is respectfully submitted that Mikhail does not describe "a *pressure actuated valve*" including "a flow control membrane... including a plurality of slits extending therethrough, wherein, *when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen,*" as recited in claim 1. Furthermore, claim 1 recites "a plurality of slits...wherein each of the slits extends between end portions thereof along a curve and *wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits is a minimum*

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distance between the first and second slits." This configuration of slits is most simply illustrated by Fig. 5 of the instant application. In contrast, none of the slit configurations shown in Mikhail include a plurality of slits with each of the slits extending "between end portions thereof along a curve and wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits is a minimum distance between the first and second slits," as recited in claim 1. (See Mikhail, Figs. 21-35.) Because claims 2 - 9 depend from, and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 10 recites a flow control device for a pressure actuated valve, comprising "a substantially planar elastic membrane including a peripheral seating portion adapted to be secured to a housing of the pressure actuated valve and a central portion including a first curved slit extending therethrough, the elastic membrane biasing the first slit to a closed configuration in which edges of the first slit are in contact with one another to prevent flow past the membrane, wherein, when the membrane is subject to a pressure of at least a predetermined threshold magnitude, the membrane moves to an open configuration in which the edges of the first slit are separated from one another so that fluid may flow past the membrane through the first slit. flow control device comprising "a substantially planar elastic membrane." It is respectfully submitted that this claim is allowable for the same reasons stated above in regard to claim 1. In addition, it is noted that each of the valves of Mikhail is a "dome-type" valve. (Mikhail, col. 27, ll. 6-55; Fig. 3.) That is, the valves are dome shaped and are not substantially planar as recited in claim 10. Because claims 11 - 16 depend from, and, therefore, include all of the limitations of claim 10, it is respectfully submitted that these claims are also allowable.

Claim 17 recites a catheter comprising "a pressure actuated valve" including "a flow control membrane extending across the lumen, the membrane including a first curved slit extending therethrough, wherein... when the membrane is subject to a pressure of at least a predetermined threshold magnitude, the membrane deforms to an open configuration in which

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edges of the first slit separate from one another to all flow through the lumen." It is respectfully submitted that claim 17 is allowable for the same reasons stated above in regard to claim 1.

Because claims 18 and 19 depend from, and, therefore, include all of the limitations of claim 17, it is respectfully submitted that these claims are also allowable.

Claim 20 recites a valve including "a flow control membrane extending across a lumen of the device, the membrane including a plurality of slits extending therethrough, the slits being configured so that, *when the membrane is subjected to a flow pressure of at least a threshold magnitude*, the slits open to permit flow through the lumen..." It is respectfully submitted that this claim is allowable for the reasons stated above in regard to claim 1.

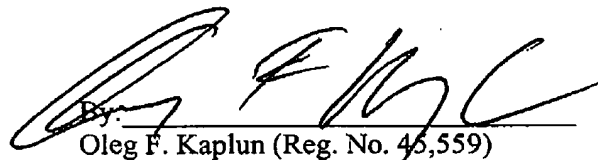
Claim 21 recites a catheter including "a flow control membrane extending across a lumen thereof to regulate flow through the lumen and to seal the catheter when not in use, the membrane including a first curved slit extending therethrough, the slit being configured so that... *when the membrane is subject to a flow pressure of at least the predetermined threshold magnitude*, the edges of the slit separate from one another to permit flow past the membrane." It is respectfully submitted that this claim is allowable for at least the reasons stated above in regard to claim 1.

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It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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